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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,687	08/31/2001	Kamel F. Egbaria	MGP-104US	1264

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,687	EGBARIA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3,4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT TO INFROMATION DISCLOSURE STATEMENT (IDS) AND STATUS OF THE CLAIMS

1. The information disclosure statements (IDS) and Form PTO-1449 filed 3/1/02, 4/5/02, 9/3/02 and 9/22/03 are acknowledged, entered and considered. Claims 1-30 are now present in the application.

CLAIMS REJECTION-35 U.S.C. § 103(a)

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al., (U.S. Patent No. 5,962,019) taken with Li et al., (S.T.P. Pharma Sciences, Vol. 10, No. 4, pp. 341-344, 2000) and Kovacs et al., (U.S. Patent No. 5,583,105).

Cho et al., teach an orally administered pharmaceutical composition comprising cyclosporin (including cyclosporin A), ethanol, polyoxyethtylene compounds and polyoxyethylene derivatives of fatty acids (which includes polyoxyethylene glycerol trioleate), and an oil component (such as ethyl oleate) and a method of preparing such pharmaceutical formulation thereof. The reference discloses various concentrations for oral cyclosporin formulation, wherein the preferred concentration for cyclosporin A ranges from 50 to 150 mg/ml, for alkanols such as ethanol ranges from 5 to 60% (v/v), for oil component such as ethyl oleate ranges from 15 to 75% (v/v), and for polyoxyethylene compounds or derivatives thereof ranges from 5 to 60% (v/v). (See cols. 3-7 and the claims) as directed to claims 1-13 and 18-26.

The reference of Cho et al., differs from claims 1-30 in not teaching the formulation of spontaneous emulsion with the diameter of the particles of said spontaneous emulsion and the specific concentrations and ratios recited in the claims. As acknowledged in the instant specification on page 2, lines 3-15, cyclosporin is highly lipophilic and hydrophobic, and as such sparingly soluble in water and well dissolved in organic solvents. However, the secondary reference of Li et al., teaches that self-emulsifying drug deliver systems (SEDDS) are a convenient method of delivering hydrophobic drugs, especially if they are unstable in water in the presence of water (See e.g., pages 341-344) as directed to claims 16-17 and 28-30. Thus, the reference clearly teaches the influence of oleic acid on the formation of a spontaneous emulsion. Although, the prior art of Li et al., does not disclose the diameter of the particle size of the spontaneous emulsion, nevertheless, the prior art states that the particle size were

performed on a Nicomp 370 sizer at room temperature. Thus, clearly suggesting or contemplating the particle size measurement.

With respect to the selection of specific concentrations and ratios as recited in the claims, although, all the references show the ranges claimed, however, Kovacs et al., discloses the specific and preferred concentration ranges and ratios as claimed in the instant invention (See e.g., cols. 1-4 and claims 1 and 8-12) as directed to claims 1-15 and 18-27. Thus, the ranges disclosed in the prior art and claimed by Applicant overlap in scope, and as such, the selection of the appropriate concentrations, diameters, and ratios would have been *prima facie* obvious because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation, *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1995).

Therefore, in view of the above and in view of the combined teachings of the prior art makes obvious the claimed invention's orally administered pharmaceutical composition in a form of a spontaneous emulsion comprising cyclosporin (cyclosporin A), ethanol, polyoxyethylene glycerol trioleate, and an oil component (ethyl oleate) and a method of preparing such pharmaceutical formulation thereof, absent of objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-1923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AAM Mohamed/AAM

September 30, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600